STATEMENT

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In Opposition to Connecticut House Bill 6619
February 14, 2023

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) opposes House Bill 6619, legislation to make certain patent settlement agreements presumptively anticompetitive.

Discussions about the cost and affordability of medicines are important. No patient should have to worry about whether they can afford the health care they need. House Bill 6619 seeks to inject state authority into patent settlement agreements, ignores the federal standard for evaluation of these agreements and may have the unintended consequence of delaying generic market entry. For the reasons detailed below, PhRMA urges legislators to oppose HB 6619.

Patent settlements are an expected result of the framework that Congress created in the Hatch-Waxman Act to resolve patent disputes and generally permit generic drugs and biosimilar products on the market earlier than patent expiration, generating significant savings for consumers. Patent settlements do not extend the patent term of an innovator's drug and therefore, do not lead to generic entry past patent expiry of the innovator's drug. According to one generic company's estimate, settlements on 10 products alone allowed generic launches an aggregate of 83.4 years before patent expiration, resulting in more than $67 billion in savings to consumers[1]. Legislation restricting certain kinds of pharmaceutical patent settlements could prevent some pro-consumer settlements, reduce the value of patents, and reduce incentives for innovation.

HB 6619 displaces the Federal Trade Commission's (FTC) role in policing patent settlement agreements. As currently written, this bill is inconsistent with the approach of the U.S. Supreme Court in *FTC v. Actavis*, which established the standard under which the FTC and courts review patent settlement agreements. The FTC can review and take enforcement action against individual patent settlements under the U.S. Supreme Court's holding in *Actavis*, which provided for use of a "rule of reason" to determine whether a patent settlement agreement is anticompetitive. Since 2003, Congress has required pharmaceutical manufacturers to submit to the FTC certain agreements between manufacturers of new drugs and generic products, and Congress expanded this requirement in 2018, further enabling the FTC's review of these agreements. HB 6619 creates a different standard under Connecticut law for assessing the appropriateness of settlement agreements. This inconsistency creates significant uncertainty for stakeholders and subverts the roles of the FTC and federal courts. In addition, HB 6619 limits the fact-finder with respect to the facts he/she can presume. The fact-finder in litigation should make appropriate determinations based on the circumstances of the case, consistent with U.S. Supreme Court precedent and longstanding antitrust law.

Modifying the standard for evaluation of patent settlement agreements could have a substantial chilling effect on procompetitive settlements that generate savings for consumers via earlier generic entry prior to patent expiration. Deterring procompetitive patent settlements could also lead to delayed generic entry by forcing generic companies to take complex patent challenges all the way to a court decision,

[1] Testimony of Theodore C. Whitehouse of Wilkie, Farr, & Gallagher LLP on behalf of Teva Pharmaceuticals USA, Inc., for House E&C Comm., Subcommittee on Commerce, Trade, and Consumer Protection Hearing on H.R. 1706, "Protecting Consumer Access to Generic Drugs Act of 2009," Mar. 31, 2009.

risking that the competing generic medicine remains off the market entirely until patent expiration. This point is increasingly important as the volume of litigation in this space has increased dramatically. For all new molecular entities, just 9% of drugs experiencing first generic entry in 1995 had faced any patent challenge under Hatch-Waxman (referred to as a Paragraph IV challenge) by the time of the launch of the first generic. For drugs experiencing first generic entry in 2019, the figure had increased to 81% and for drugs with sales greater than $250 million, the probability of facing a Paragraph IV challenge reached 93% for drugs experiencing first generic entry in 2019[2]. Discouraging settlements to this litigation is counter to the intent of the bill, which is to ensure access to generic alternatives, because patent settlement agreements inject certainty into patent disputes that is thwarted by costly and complex litigation.

In fact, historical data show that patent settlements have not increased the average market exclusivity period for innovator drugs. As noted in an article examining this issue, "the average length of market exclusivity for drugs experiencing first generic entry in 1995 to 1996 was 13.5 years. During this period conveyances of consideration from patent holders to generic companies as part of settlement agreements occurred infrequently. Over time, more patent infringement settlements have included 'reverse payment.' Yet the average length of market exclusivity has decreased. For drugs experiencing first generic entry in 2011-2012, for example, average market exclusivity was 12.9 years."[3] An analysis of more recent data shows that, on average, the market exclusivity period for brand drugs has changed relatively little over the past decade. For drugs experiencing initial generic entry in 2017 – 2019, the average market exclusivity period was 13 years for drugs with sales greater than $250 million and 14.1 years overall.[4] According to the Association for Accessible Medicines (formerly the Generic Pharmaceutical Association), "patent settlements have enabled dozens of first-time generics to come to market many months and even years before patents on the counterpart brand drugs expired."[5]

Finally, the bill is vulnerable to the same type of constitutional challenge that the Association for Accessible Medicines (AAM) brought against California's very similar law, Assembly Bill No. 824 (AB 824), in which the district court observed that "if the Attorney General were to enforce the terms of AB 824 against two out of state parties that entered into a settlement agreement outside of California, having nothing to do with California, such conduct would likely violate the Dormant Commerce Clause."

PhRMA represents the country's leading innovative biopharmaceutical research and biotechnology companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. PhRMA appreciates efforts to ensure access to medicines and is happy to be part of a conversation as to how best to serve patients; however, this bill has the potential to restrict earlier access to generic alternatives and is not consistent with U.S. Supreme Court precedent and for those reasons, **PhRMA urges Connecticut legislators to oppose HB 6619**.

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[2] Henry Grabowski, Genia Long, Richard Mortimer & Mehmet Bilginsoy. "Continuing trends in U.S. brand-name and generic drug competition," *Journal of Medical Economics*, August 2, 2021. https://doi.org/10.1080/13696998.2021.1952795

[3] L. E. John, et al., "Reverse Payment Realities: Challenging Pervasive Assumptions Underlying Calls for Broad Antitrust Scrutiny of Patent Infringement Settlements," Bloomberg BNA, November 13, 2014.

[4] Henry Grabowski, Genia Long, Richard Mortimer & Mehmet Bilginsoy. "Continuing trends in U.S. brand-name and generic drug competition," *Journal of Medical Economics*, August 2, 2021. https://doi.org/10.1080/13696998.2021.1952795

[5] Generic Pharmaceutical Association, Press Release, Appeals Court Ruling Threatens Consumer Access to Safe and Effective Generic Drugs. July 16, 2012.